BIOENGINEERING NANOTECHNOLOGY INITIATIVE (supercedes PA-00-018)

RELEASE DATE: July 2, 2002 (see also PA-00-018)

PA NUMBER: PA-02-125

EXPIRATION DATE: June 3, 2005, unless reissued.

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(http://www.nlm.nih.gov/)

THIS PA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS PA

This Program Announcement (PA), issued as an initiative of the trans-NIH Bioengineering Consortium (BECON), invites grant applications for Small Business Innovation Research (SBIR) projects on nanotechnologies useful to biomedicine. Nanotechnology is defined as the creation of functional materials, devices and systems through control of matter at the scale of 1 to 100 nanometers, and the exploitation of novel properties and phenomena at the same scale. Nanotechnology is emerging as a field critical for enabling essential breakthroughs that may have tremendous potential for affecting biomedicine. Moreover, nanotechnologies developed in the next several years may well form the foundation of significant commercial platforms.

In recognition of the nascence of this area, the duration and amounts of individual grants awarded under this PA may be greater than those routinely allowed under the SBIR program. Few small businesses possess the highly specialized resources needed for nanoengineering. Therefore, this PA encourages team approaches to research in the belief that a synergistic blend of

expertise and resources may be needed to allow for strong partnerships between the small businesses and other entities in Phase I. Applications are encouraged from teams of investigators from commercial, academic and other sectors of the research community. Partners to the small businesses may play important roles in these projects and may receive appropriate support for their efforts. In addition to requiring collaboration from various sectors, it is expected that this initiative will require expertise from a variety of disciplines, including engineering, chemistry, physics, material science, engineering, and biology.

This PA must be read in conjunction with the current Omnibus Solicitation of the Public Health Service (Omnibus Solicitation) for Phase I SBIR Grant Applications available at http://grants.nih.gov/grants/funding/sbir.htm

RESEARCH OBJECTIVES

Background

Nearly half a century ago, the finest minds in physics disagreed as to whether it would ever be possible to manipulate individual atoms and electrons. Today, the amount of nanoscale science and engineering is exploding because of the availability of new investigative tools. These new analytical tools are capable of probing the nanometer world and will make it possible to characterize chemical and mechanical properties of cells, discover novel phenomena and processes, and provide science with a wide range of tools, materials, devices, and systems with unique characteristics. For example, complementing optical traps and tweezers, nanoscale carbon tubes are ideal probe tips for scanning microscopy, and could be used to better understand the structure of biomolecules. Carbon nanotubes with bioactive tips could be used to serve as chemically-selective grips for particular, individual molecules. This capability could be used, in turn, to manipulate and observe directly interactions between individual molecules (e.g., proteins) and to detect different biological agents and pathogens thus revolutionizing the use of probe microscopy in chemistry and biology. Indeed, by using diverse tools and concepts such as scanning probe manipulators, nanolithography, and self-assembling molecular properties, it should be possible to arrange individual atoms and molecules in space with great precision, leading to the fabrication of truly smart biosensors.

On the other hand, complex biological systems provide models from which to design components that can be brought together to form three-dimensional nanostructured systems. For example, the properties of DNA to undergo highly controlled and hierarchical assembly makes it ideal for applications in nanotechnology such as molecular sieves, or scaffolds for the assembly of

molecular electronic components. Likewise, eukaryotic rotary motors based on ATPase could be employed as generic engines driving other nanodevices for purposes such as highly directed delivery of drugs or other agents.

Eventually, by coupling advances in the knowledge of living systems with the unique capabilities imparted by nanostructures and materials, it may be possible to detect and intervene in disease states using biologically inspired solutions. Integration of biocompatible materials with fluidics, optics, mechanical and electronic components, all at micro- to nano- scale, will enable development of implantable noninvasive sensing systems for the detection and prevention of disease at the earliest stages of its development. Controlled release delivery systems will make possible delivery of both conventional and new, nanostructured drugs at targeted specific sites in the body, while nanoscale chemical and topographical details on the surface of implantable materials will mediate their reaction with the body. Nanotechnology promises scientific and commercial opportunities that are virtually unimaginable at this time.

Research Topics

BECON has identified a number of priority areas for nanoscience and nanotechnology research support at NIH. This list is not exhaustive, nor are the topics mutually exclusive. Their presentation here exemplifies important scientific areas in which research at the nanoscale has the potential to make enormous contributions to solving biomedical problems.

o Nanomaterials (enabling): nano materials science for interfacing with living tissues, passive delivery of pharmaceuticals, tissue engineering scaffolds, contrast and biological agents, and medical devices.

o Nanoimaging: real-time subcellular imaging of structure, function, properties and metabolism.

o Cell biology: nano-scale research on cellular processes, including biophysics of molecular assemblies, membranes, organelles, and macromolecules.

o Molecular and cellular sensing/signaling: technologies to detect biological signals and single molecules within and outside cells.

o Nanomotors: understanding structure/function and self-assembly; primary and secondary power supply.

o Prosthetics: mechanical, chemical, and cellular implant nano-technologies to achieve functional replacement tissue architectures.

o Nanobioprocessor: implantable nano scale processors that can integrate with biological pathways and modify biological processes.

o Nanosystem design and application: fundamental principles and tools to measure and image the biological processes of health and disease; and methods to assemble nanosystems.

Examples of general research topics that would be considered responsive to this PA are listed below. This is not meant to be an exhaustive, exclusive or delimiting set of topics, rather these merely represent illustrations of projects that would be considered relevant to this PA.

o Nanoplumbing components such as valves, microfluidic channels, and motors (e.g., to be used as pumps)

o Development and improvement of techniques based on new principles for probing biological properties and phenomena not well understood at the nanometer scale and for characterizing nanoscale materials

o Development of fluorescent probes at the nanometer scale for monitoring biochemical processes on the surface and inside a cell in health and disease

o Creation of "smart" nanostructured biocompatible materials. Approaches may include self-assembling techniques and supramolecular chemistry for building up functional nanostructures and for modifying and patterning material surface texture

o Development of nanofabricated barriers to prevent rejection of implantable materials

o Development of nanoparticles and nanospheres that enable controlled released of therapeutic agents, antibodies, genes and vaccines into targeted cells

o Development of sensor technologies for detection and analysis of biologically relevant molecular and physical targets in samples from blood, saliva and other body fluids, or for use in the research laboratory (purified samples), clinical specimens and in the living body.

MECHANISM OF SUPPORT - PHASE I

Phase I applications in response to this PA will be funded as Phase I SBIR Grants (R43). As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

Project Period and Amount of Award

Because the duration and cost of research to develop nanotechnologies are likely to exceed that routinely awarded for SBIR grants, well-justified Phase I applications under this PA will be considered with a project period up to two years and a budget not to exceed a total cost of $400,000 (i.e., an average of $200,000 per year).

Consultant and contractual costs

Because the resources required for nanoengineering are relatively scarce, highly specialized, and multidisciplinary, the total amount of consultant costs and contractual costs requested by applicants may exceed the statutory guidelines. Requests in excess of the guidelines must be fully justified.

MECHANISM OF SUPPORT - PHASE II

Phase II applications in response to this PA will be awarded as Phase II SBIR grants (R44) with modifications as described below. Phase II applications in response to this PA will only be accepted as competing continuations of previously funded NIH Phase I SBIR awards. The previously funded Phase I award need not have been awarded under this PA but the Phase II proposal must be a logical extension of the Phase I research. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

Project Period and Amount of Award

Because the duration and cost of research to develop nanotechnologies is likely to exceed that routinely awarded for SBIR grants, well-justified Phase II applications under this PA will be considered with a project period up to three years and a budget not to exceed a total cost of $1,200,000 (i.e., an average of $400,000 for each of three years).

Consultant and Contractual Costs

Because the resources required for nanoengineering are relatively scarce, highly specialized, and multidisciplinary, the total amount of consultant costs and contractual costs requested by applicants may exceed the statutory guidelines. Requests in excess of the guidelines must be fully justified.

ELIGIBLE INSTITUTIONS

Eligibility requirements for Phase I and Phase II grants are found at http://grants.nih.gov/grants/funding/sbirsttr1/index.pdf.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

NCI – Ed Monachino, Ph.D.; National Cancer Institute; Building 31, Room 10A49, MSC 2580, Bethesda, MD 20892-2580; Telephone: (301) 496-1550; FAX: (301) 496-7807; Email: monachie@mail.nih.gov

NEI – Richard S. Fisher, Ph.D.; National Eye Institute; Executive Plaza South, Suite 350; 6120 Executive Boulevard, MSC 7164; Bethesda, MD 20892-7164; Telephone: (301) 451-2020; FAX: (301) 402-0528; Email: rf75s@nih.gov

NHLBI – NHLBI - John T. Watson, Ph.D.; National Heart, Lung, and Blood Institute; 6701 Rockledge Drive, Room 9166; Bethesda, MD 20892-7940; Telephone: (301) 435-0555; FAX: (301) 480-7971; Email: jw53f@nih.gov

NHGRI - Jeffery A. Schloss, Ph.D.; Division of Extramural Research; National Human Genome Research Institute; Building 31, Room B2B07, MSC 2033; Bethesda, MD 20892-2033; Telephone: (301) 496-7531; FAX: (301) 480-2770; Email: jeff_schloss@nih.gov

NIA – Winifred K. Rossi, M.A.; Geriatrics and Clinical Gerontology; National Institute on Aging; Gateway Building, Suite 3E327, MSC 9205; Bethesda, MD 20892-9205; Telephone: (301) 496-3836; FAX: (301) 402-1784; Email: Email: rossiw@nia.nih.gov

NIAAA -Michael Eckardt, Ph.D.; Office of Scientific Affairs; Institute on Alcohol Abuse and Alcoholism; Suite 409; 6000 Executive Blvd.; Bethesda, MD 20892-7003; Telephone: (301) 443-6107; Fax: (301) 443-6077; Email: me25t@nih.gov

NIAID – Maria Y. Giovanni, Ph.D.; Division of Microbiology and Infectious Disease; National Institute of Allergy and Infectious Diseases; 6700-B Rockledge Dr. MSC 7630; Bethesda, MD 20892-7630; Telephone: (301) 496-1884; FAX: (301) 480-4528; Email: mgiovanni@niaid.nih.gov

NIAMS - James S. Panagis, M.D., M.P.H.; Orthopaedics Program; National Institute of Arthritis and Musculoskeletal and Skin Diseases; Bethesda, MD 20892-6500; Telephone: (301) 594-5055; Email: jp149d@nih.gov

NIBIB – Joan T. Harmon, Ph.D.; Division of Bioengineering; National Institute of Biomedical Imaging and Bioengineering; 6707 Democracy Boulevard, Room 956; Bethesda, MD 20892-5469; Telephone: (301) 451-4776; FAX: (301) 480-4973; Email: joan_harmon@nih.gov

NIDCD - Lynn E. Luethke, Ph.D.; National Institute on Deafness and Other Communication Disorders; 6120 Executive Boulevard, MSC 7180; Bethesda, MD 20892-7180; Telephone: (301) 402-3458; FAX: (301) 402-6251; Email: lynn_luethke@nih.gov

NIDCR - Eleni Kousvelari, D.D.S., D.Sc.; Cellular and Molecular Biology, Physiology and Biotechnology Branch; National Institute of Dental and Craniofacial Research; Natcher Building, Room 4AN 18A, MSC 6402; Bethesda, MD 20892-6402; Telephone: (301) 594-2427; FAX: (301) 480-8318; Email: kousvelari@de45.nidr.nih.gov

NIDDK - Thomas Eggerman, Ph.D.; Division of Diabetes, Endocrinology, and Metabolic Diseases; National Institute of Diabetes and Digestive and Kidney Diseases; 6706 Democracy

Blvd., Room 697, MSC 5460, Bethesda, MD, 20895-5460, Telephone: (301) 594-8813; FAX: (301) 480-3503; Email: EggermanT@extra.niddk.nih.gov

NIDA - Thomas G. Aigner, Ph.D.; Division of Basic Research; National Institute on Drug Abuse; 6001 Executive Boulevard, Room 4282, MSC 9555; Bethesda, MD 20892-9555; Telephone: (301) 443-6975; FAX: (301) 594-6043; Email: ta17r@nih.gov

NIEHS - Dr. Claudia Thompson; Division of Extramural Research and Training; National Institute of Environmental Health Sciences; PO Box 12233, Mail Drop EC-23; Research Triangle Park, NC 27709; Telephone: (919) 541-4638; FAX: (919) 541-5064; Email: ct68w@nih.gov

NIGMS –Catherine Lewis, Ph.D.; Bldg. 45, Rm 2AS-13K; 45 Center Dr.; Bethesda, MD 20892-6200; Telephone: 301-594-0828; FAX: (301) 480-2004; Email: lewisc@nigms.nih.gov

NIMH – Margaret Grabb, Ph.D.; Division of Neuroscience and Basic Behavioral Science; National Institute of Mental Health; 6001 Executive Boulevard, Room 7202, MSC 9645; Bethesda, MD 20892-9645; Telephone: (301) 443-3563; FAX: (301) 443-1731; Email: mgrabb@mail.nih.gov

NINR - Hilary Sigmon, Ph.D.; Cardiopulmonary Health & Critical Care; National Institute of Nursing Research; Building 45, Room 3AN12; 45 Center Drive; Bethesda, Maryland 20892-6300; Telephone: (301) 594-5970; FAX: (301) 480-8260; Email: hsigmon@ep.ninr.nih.gov

NLM - Susan Sparks, R.N., Ph.D., F.A.A.N; Division of Extramural Programs; National Library of Medicine; Rockledge One, Suite 301; 6705 Rockledge Drive; Bethesda, MD 20817; Telephone: (301) 594 4882; FAX: (301) 402-2952; Email: sparkss@mail.nlm.nih.gov

o Direct your questions about financial or grants management matters to:

NCI - Bill Wells; Grants Administration Branch; National Cancer Institute; 6120 Executive Boulevard, Room 243, MSC 7150; Bethesda, MD 20892-7150; Telephone: (301) 496-7800; FAX: (301) 496-8601; Email: wellsw@gab.nci.nih.gov

NEI – William Darby, Grants Management Officer; National Eye Institute; 6120 Executive Boulevard, Suite 350, MSC 7164; Bethesda, MD 20892-7164; Telephone: (301) 451-2020; FAX: (301) 402-0528; Email: wwd@nei.nih.gov

NHLBI - Jane Davis; National Heart, Lung, and Blood Institute; 6701 Rockledge Drive, Room 7174; Bethesda, MD 20892; Telephone: (301) 435-0166; FAX: (301) 480-3310; Email: jd53f@nih.gov

NHGRI - Jean Cahill; Grants Management Office; National Human Genome Research Institute; Building 31, Room B2B34; 31 Center Drive, MSC 2030; Bethesda, MD 20892-2030; Telephone: (301) 402-0733; FAX: (301) 402-1951; Email: jean_cahill@nih.gov

NIA - Linda Whipp; Grants and Contracts Management Officer; National Institute on Aging; Gateway Building, Suite 2N212; Bethesda, MD 20892; Telephone: (301) 496-1472; FAX: (301) 402-3672; Email: Whippl@nia.nih.gov

NIAAA - Judy Simons; Grants Management Officer; National Institute on Alcohol Abuse and Alcoholism; 6000 Executive Blvd., Suite 504; Bethesda, MD 20892-7003; Telephone: (301) 443-4704; Fax: (301) 443-3891; Email: jsimons@willco.niaaa.nih.gov

NIAID – Lesia Norwood; Division of Extramural Activities; National Institute of Allergy and Infectious Diseases; Room 3221, MSC-7614; 6700-B Rockledge Drive; Bethesda, MD 20892-7614; Telephone: (301) 402-6581; FAX: (301) 480-3780; Email: ln5t@nih.gov

NIAMS – Melinda Nelson; Grants Management Branch; National Institute of Arthritis and Musculoskeletal and Skin Diseases; Bethesda, MD 20892-6500; Telephone: (301) 594-3535; Email: nelsonm@mail.nih.gov

NIBIB - Ms. Annette Hanopole; Grants Management Officer; National Institute of Biomedical Imaging and Bioengineering; 6707 Democracy Boulevard; Bethesda, MD 20892-5469; Telephone: 301-451-4789; Fax: 301-480-4973; Email: hanopola@nibib.nih.gov

NIDCD - Sharon Hunt; Grants Management Branch; National Institute on Deafness and Other Communication Disorders; 6120 Executive Boulevard, Room 400-C, MSC 7180; Bethesda, MD 20892-7180; Telephone: (301) 402-0909; FAX: (301) 402-1758; Email: sharon_hunt@nih.gov

NIDCR - Kevin Crist; Division of Extramural Research; National Institute of Dental and Craniofacial Research; Natcher Building, Room 4AS 55; Bethesda, MD 20892-6402; Telephone: (301) 594-4800; FAX: (301) 480-8301; Email: Kevin.Crist@nih.gov

NIDDK - Kathleen J. Shino, MBA; Grants Management Branch; National Institutes of Diabetes and Digestive and Kidney Diseases; 6707 Democracy Blvd., Room 708; Bethesda, MD 20892; Telephone: (301) 594-8869; FAX: (301) 594-9523; Email: shinok@extra.niddk.nih.gov

NIDA - Gary Fleming, J.D., M.A.; Grants Management Branch; National Institute on Drug Abuse; 6001 Executive Boulevard, Room 3131, MSC 9541; Bethesda, MD 20892-9541; Telephone: (301) 443-6710; FAX: (301) 594-6847; Email: gf6s@nih.gov

NIEHS – Dorothy Duke; Division of Extramural Research and Training; National Institute of Environmental Health Sciences; P.O. Box 12233, Mail Drop EC-22; Research Triangle Park, NC 27709; Telephone: (919) 541-1373; FAX: (919) 541-2860; Email: Duke3@niehs.nih.gov

NIGMS - Grace Tuanmu; Grants Management, CBB; National Institute of General Medical Sciences; 45 Center Drive MSC 6200; Room 2AN.32E; Bethesda, Md. 20892-6200; Telephone: (301) 594 5520; FAX: (301) 480 2554; Email tuanmug@nigms.nih.gov

NIMH - Kathy Hancock; Grants Management Branch; National Institute of Child Health and Human Development; 6100 Executive Boulevard, Room 8A17M; Bethesda, MD 20892-7510; Telephone: (301) 496-5482; FAX: (301) 402-0915; Email: hancockk@mail.nih.gov

NINR – Cynthia McDermott; Office of Grants and Contracts Management; National Institute of Nursing Research; Building 45, Room 3AN12; 45 Center Drive; Bethesda, Maryland 20892-6300; Telephone: 301-594-6869; FAX: 301-480-8260; Email: mcdermot@mail.nih.gov

NLM – J. Christopher Robey, M.A; Division of Extramural Programs; National Library of Medicine; Rockledge One, Suite 301; 6705 Rockledge Drive; Bethesda, MD 20817 (For courier delivery service use: 20817); Telephone: (301) 594-4937; FAX: (301) 402-0421; Email: robeyj@mail.nlm.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. Suggest cite specific Small Business Section. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

For purposes of identification and processing, the title and number of this PA must be shown in item 2 on the face page of the application (i.e., "BIOENGINEERING NANOTECHNOLOGY INITIATIVE," PA-02-125)

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at http://grants.nih.gov/grants/dates.htm. Application deadlines are also indicated in the PHS 398 application kit.

Not for small business; have set separate budget limits anyway.
SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received by or mailed on or before the receipt dates described at http://grants.nih.gov/grants/funding/submissionschedule.htm. The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures (http://www.csr.nih.gov/refrev.htm) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

o Receive a written critique

o Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
o Receive a second level review by the appropriate national advisory council or board

REVIEW CRITERIA

Review criteria are described in the Omnibus Solicitation (http://grants1.nih.gov/grants/funding/sbirsttr1/section_6.html).
The Phase I application should specify clear, measurable goals (milestones) that should be achieved prior to initiating Phase II. Failure to provide clear, measurable goals may be sufficient reason for the study section to judge the application non-competitive.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

o Scientific merit of the proposed project as determined by peer review
o Availability of funds
o Relevance to program priorities

REQUIRED FEDERAL CITATIONS

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html);
a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://grants.nih.gov/grants/stem_cells.htm and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide the official NIH identifier(s)for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT:
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public

access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance No. 93.394 (NCI); 93.387 (NEI); 93.233, 93.837, 93.838, 93.839 (NHLBI); 93.172 (NHGRI); 93.866 (NIA); 93.271 (NIAAA); 93.856 (NIAID); 93.846 (NIAMS); 93.286, 93.287 (NIBIB); 93.173 (NIDCD); 93.121 (NIDCR); 93.849, 93.848 and 93.847 (NIDDK); 93.279 (NIDA); 93.114 (NIEHS); 93.821, 93.859, 93.862 (NIGMS); 93.242 (NIMH); 93.361 (NINR); 93.879 (NLM) and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at http://grants.nih.gov/grants/policy/policy.htm and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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